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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420
7590	03/16/2004		EXAMINER	
Lisa A. Amii Morrison & Foerster LLP 755 Page Mill Road Palo Alto, CA 94304-1018			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/081,050	OSBORNE, DAVID W.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 December 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1, 4, 7-22 and 25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 4, 7-22 and 25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of amendment and response dated 12-8-03 is acknowledged.

Claims 2, 3, 5, 6, 23, 24 and 26 have been canceled.

Instant claims are amended to recite a method of reducing the number of non-inflammatory acne or a method of treating non-inflammatory acne comprising a step of topically applying a dermatological composition comprising dapsone to the non-inflammatory acne lesions.

The rejection of record (dated 7-11-03) has been maintained for the following reasons:

*Claim Rejections - 35 USC § 102*

Claims 1-7, 13, 14, 20, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 or US 5,863,560, both patented to Osborne ('085 and '560).

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references teach dapsone in a topical composition and for the same purpose i.e., treatment of acne. Accordingly, the ability to treat inflammatory and non-inflammatory acne is inherent to the composition of both the references. Osborne also discloses the method of preparing the dapsone composition involving the claimed steps (col. 7, lines 10-25 of both patents). With respect to the

method of preventing non-inflammatory acne lesion from becoming inflammatory acne, the dissolved portion of dapsone in the composition of Osborne passes through stratum corneum in to lower third of pilosebaceous unit, whereas the microparticulate dapsone crosses stratum corneum only minimally. Thus, once the herpes lesion vesicle ruptures and the stratum corneum is no longer in place, then the microparticulate dapsone is only dissolved and is released for sustained and significant therapeutic benefit, thus preventing the development of inflammatory lesion (col. 2). Therefore, Osborne ('085 and '560) anticipates the instant claimed invention.

***Claim Rejections - 35 USC § 103***

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,964 to Singleton et al ('964) in view of Osborne ('085 or '560).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. However, '964 fail to explicitly teach dapsone for treating acne.

The teachings of Osborne ('085 and '560) have been discussed above. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to use dapsone in the composition of '964 as an additional anti-acne agent because Osborne teaches dapsone as an effective anti-acne agent and using dapsone in an dissolved and a microparticulate forms in the same composition enables immediate treatment of inflammation as well as prevention of

inflammatory lesions. Further, preparing the dapson containing composition in the different formulations such as a cream, lotion, gel without loosing the anti-acne activity would have been within the scope of a skilled artisan.

*Response to Arguments*

Applicant's arguments filed 12-8-03 have been fully considered but they are not persuasive.

In view of the amendment and cancellation of claims, the rejections of claims under 35 USC 112, first and second paragraphs have been withdrawn.

**Claim Rejections - 35 USC § 102:**

Applicants argue that Instant claim 1 now recites a method “for reducing the number of non-inflammatory acne lesions”, which has not been taught or disclosed by both Osborne patents (‘085 and ‘050). Applicants argue that not all acne is the same, some result in inflammation and inflammatory lesions, while other acne does not. Applicants argues that Osborne patents cited under 35 USC § 102 fail to disclose even a single instance of treating non-inflammatory acne lesions with a dermatological composition, let alone for reducing the number of non-inflammatory acne lesions. Applicants further argue that examiner failed to provide a basis in fact and, or, technical reasoning to reasonably support a conclusion that an allegedly inherent characteristic “necessarily flows” from the teachings of the cited art and an evidence for the basis. Applicants argue that instant new use of a known composition, based on unknown properties are patentable. Therefore, applicant states that the instant claims are patentable.

However, applicants arguments are not found persuasive because the prior art references teach the same active agent dapsone, formulated in the same manner as claimed i.e., comprising dissolved and microparticulate dapsone. Osborne patents teach that intact stratum corneum lines the upper third of the pilosebaceous unit into which the sebaceous duct secrete sebum. Further, Osborne patents teach that dapsone formulation is largely delivered in this sebum secreting duct and also cross this region (col. 1-2). Acne is a known multifactorial disease that involves increased amounts of sebum production in the sebaceous follicles resulting in hyperkeratosis of the follicular epithelium, which in turn leads to the obstruction of the duct by horny plaque and formation of a non-inflammatory comedones. It is implicit from the teachings of Osborne patents that dapsone formulation delivered to that same portion of pilosebaceous unit, where the process of forming non-inflammatory comedones begins. Therefore, it is inherent that the dapsone formulation of Osborne patents possesses the ability to reduce the number of non-inflammatory acne lesions formed and thus provides a treatment for non-inflammatory acne lesions. Further, on Page 5 of the instant specification, applicants also describe that the claimed composition provides greatest amount of pharmaceutical available for immediate partition out of the stratum corneum and into the epidermis. Therefore, Osborne patents anticipate instant claims.

**Claim Rejections - 35 USC § 103**

Applicants argue that the instant rejection fails to teach or suggest each and every claim limitation because neither of the Osborne patents expressly or inherently teach or disclose methods for treating non-inflammatory acne and that the rejections concludes by making a reference only to the treatment of inflammation and inflammatory lesions. Applicants did not

argue the teachings of Singleton ('964). With respect to Osborne patents, examiner provided a detailed technical basis for concluding the dapsonc composition of Osborne patents inherently possess the property of reducing the number of non-inflammatory acne lesions. As explained, dapsonc is taught be delivered at the very upper third stratum corneum portion of the pilosebaceous unit, where the excess sebum production first results in non-inflammatory comedones, which then proceeds to form inflammatory comedones upon infection. Applicants also teach in the instant specification that the instant method of treatment and/or reducing non-inflammatory acne lesions is achieved by the same mechanism of delivery. Accordingly, it is examiner's position that the mechanism of action being same in the instant and the cited patents, the latter anticipates the instant invention. Accordingly, for the reasons set forth, instant claims are obvious over Singleton ('94) in view of Osborne patents ('085 or '560).

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

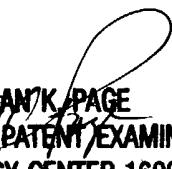
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
March 14, 2004



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